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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,751	02/09/2005	Alessandro Abbotto	NAG-10302/50	2838

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Gifford Krass Groh Sprinkle Anderson & Citkowski
P O Box 7021
Troy, MI 48007-7021

EXAMINER

MABRY, JOHN

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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11/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,751

Applicant(s)

ABBOTTO ET AL.

Examiner

John Mabry, PhD

Art Unit

4133

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/28/05 & 2/09/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

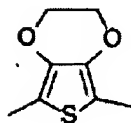
Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

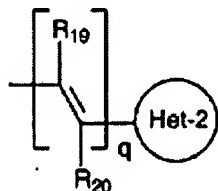
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 17, 19, 22, 24, 25, 26, 30, 32, 33, 34, 35, 36 and 37 are drawn to compounds of Formula I, wherein Het-2=pyridinium, n and m=1, R₁, R₂, R₃, R₄=H, alkyl and Het-1 and Het-3=



A further election of single disclosed species is required.

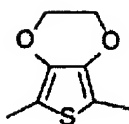
- II. Claims 18, 20, 21, 23, 27, 28 and 29 are drawn to compounds of Formula II, wherein Het-2=pyridinium, n, m, p=1, Het-1, Het-3 and Het-4=pyrrolyl. Het-4=pyrrolyl can be substituted with



wherein Het-2=pyridinium, q=1, and R₁₉, R₂₀=H, alkyl. A further election of single disclosed species is required.

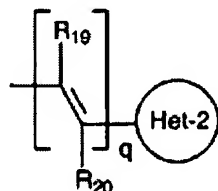
- III. Claims 17-29 are drawn to compounds of Formula I and II that are not encompassed by Groups I and II. A further election of single disclosed species is required. This group may be subject to further restriction.

- IV. Claims 30, 32, 33, 34, 35, 36 and 37 are drawn to compositions of Formula I, wherein Het-2=pyridinium, n and m=1, R₁, R₂, R₃, R₄=H, alkyl and Het-1 and Het-3=



A further election of single disclosed species is required.

- V. Claims 31, 38, 39, 40, 41, 42 and 43 are drawn to compositions of Formula II, wherein Het-2=pyridinium, n, m, p=1, Het-1, Het-3 and Het-4=pyrrolyl. Het-4=pyrrolyl can be substituted with



wherein Het-2=pyridinium, q=1, and R₁₉, R₂₀=H, alkyl. A further election of single disclosed species is required.

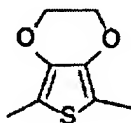
- VI. Claims 30-43 are drawn to compositions of Formula I and II that are not encompassed by Groups I and II. A further election of single disclosed species is required. This group may be subject to further restriction.

Note: The Examiner interprets claims 22-43 strictly as claims drawn strictly to compounds and compositions regardless of their intended use.

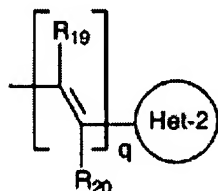
The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The special technical feature corresponding to Group I is a multiple heteroaromatic structure wherein the compounds consists of Het-2=pyridinium, n and m=1, R₁, R₂, R₃, R₄=H, alkyl and Het-1 and Het-3=

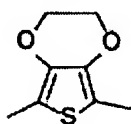


Group II contains compounds of multiple heteroaromatic structures as its special technical feature, wherein Het-2=pyridinium, n, m, p=1, Het-1, Het-3 and Het-4=pyrrolyl and can be substituted with

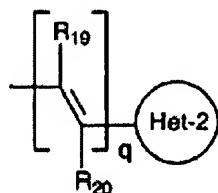


wherein Het-2=pyridinium, q=1, and R₁₉, R₂₀=H, alkyl. Group III contains to compounds of Formula I and II that are not encompassed by Groups I and II.

The special technical feature corresponding to Group IV is compounds of multiple Heteroaromatic structures wherein wherein Het-2=pyridinium, n and m=1, R₁, R₂, R₃, R₄=H, alkyl and Het-1 and Het-3=

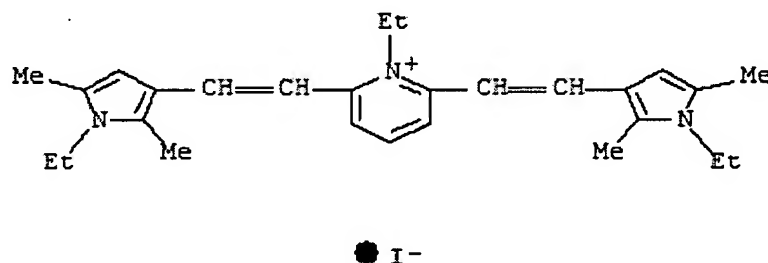


Group V contains compositions of multiple heteroaromatic structures as its special technical feature, wherein Het-2=pyridinium, n, m, p=1, Het-1, Het-3 and Het-4=pyrrolyl can be substituted with



wherein Het-2=pyridinium, q=1, and R₁₉, R₂₀=H, alkyl. Group VI contains to compositions of Formula I and II that are not encompassed by Groups I and II. These ring systems and compositions thereof are not considered equivalent.

The special technical feature of this invention is the common core found in Formula I. This special technical feature, found in US 3,376,297 A as described by Phillips et al (column 4, Table II, Example 27).



Therefore the above claims, are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a common core structure and the technical features present fail to define a contribution over the

prior art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to only one invention.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election

A telephone call was made to Kevin MacKenzie on November 12, 2007 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Rejoinder Advisory

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 24, 25, 26, 30, 32, 33, 34, 35, 36 and 37 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 22, 24, 25, 26, 30, 32, 33, 34, 35, 36 and 37 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Dependent claims 22, 24, 25, 26, 30, 33, 35, 36 and 37 are compound and composition claims which states a mode of actions such as absorption of photons by a chromophore in solution or solid state, in an absorption system, for use as a optical power limiting agent. Never the less, these claims are considered compound/composition claims that are dependent on and does not further limit claim 17.

Claims 23, 27-29, 31 and 38-43 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 3. When two claims in an application are duplicates or

else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 23, 27-29, 31 and 38-43 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Dependent claims 23, 27-29, 31 and 38-43 are compound and composition claims which states a mode of actions such as absorption of photons by a chromophore in solution or solid state, in an absorption system, for use as a optical power limiting agent. Never the less, these claims are considered compound/composition claims that are dependent on and does not further limit claim 18.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of an intended use, chemical activity or functional description of some "additional" property for a compound (or moiety/functionality attached to the chemical core) or composition containing same in dependent claim, must result in a tangible structural difference between the product of the independent claim and the product set forth in the dependent claim. In the absence of said structural difference between the product of the independent claim and that of the dependent claim, said dependent claim is seen to be a substantial duplicate, and the said recitation is not afforded critical weight and fails to further limit the product in said dependent claim.

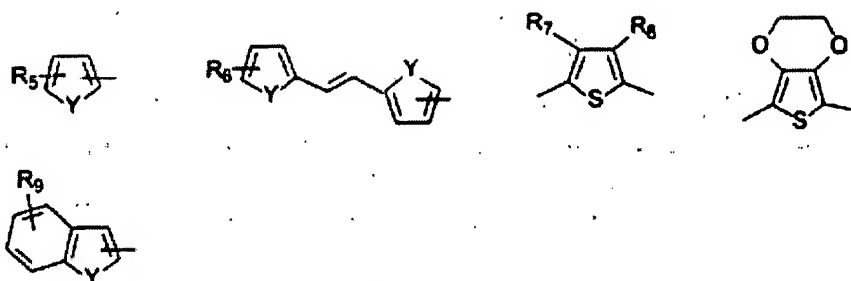
Claims 22-43 are vague and indefinite in that the claim provides for the use of claimed compounds and compositions, but the claim does not set forth any steps involved in determining the absorption of photons by a chromophore in solution or solid state, in an absorption system, for use as an optical power limiting agent and so on as stated by the claims therein.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

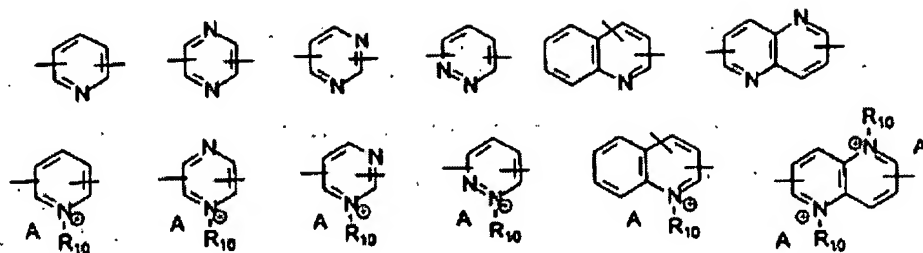
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Het-2 being N-alkylated pyridinium, Het-1, Het-3, Het-4 being thienyl fused dioxanyl, pyridinium, and pyrrolyl does not reasonably provide

enablement for Het-1, Het-2, Het-3, Het-4 being the following along with all substituted variants:



wherein Y may be O, S, or NZ with Z = H, lower alkyl, and aryl; and wherein R₅, R₆, R₇, R₈, and R₉ are the same or different, and are selected from the group consisting of H, alkyl groups having from 1 to 18 carbon atoms, alkoxy, aminoalkyl, alkylhalide, hydroxyalkyl, alkyl groups containing hydroxy and amino functionalities, alkoxyalkyl, alkylsulfide, alkylthiol, alkylazide, alkylcarboxylic, alkylsulfonic, alkylisocyanate, alkylisothiocyanate, alkylalkene, alkylalkyne, aryl, formyl, and that can contain electronpoor ethenyl moieties such as maleimide, capable to react with nucleophilic groups such as -SH, and groups such as isothiocyanate capable to react with groups such as -NH₂; and Het-2 is selected among the following heterocyclic groups:



wherein R₁₀ is selected from the group consisting of H, alkyl groups having from 1 to 18 carbon atoms, alkoxy, aminoalkyl, alkylhalide, hydroxyalkyl, alkyl groups containing hydroxy and amino functionalities, alkoxyalkyl, alkylsulfide, alkylthiol, alkylazide, alkylcarboxylic, alkylsulfonic, alkylisocyanate, alkylisothiocyanate, alkylalkene, alkylalkyne, aryl, formyl, and that can contain electronpoor ethenyl moieties such as maleimide, capable to react with nucleophilic groups such as -SH, and groups such as isothiocyanate capable to react with groups such as -NH₂;

and A is selected among the anions alkylsulfonate, arylsulfonate, polyarenesulfonate, triflate, halide, sulfate, methosulfate, phosphate, polyphosphate;

and wherein n and m, the same or different may be 0,1,2;

and R₁, R₂, R₃, and R₄, the same or different, may be H, lower alkyl, alkoxyalkyl, aryl, cyano, alkoxycarbonyl, -(CR₁₁R₁₂)_p-Het, wherein 0<p<10, R₁₁ and R₁₂, the same or different, are selected from the group of H, lower alkyl, and Het may be Het-1 or Het-2 or Het-3.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention

based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(1) Breadth of claims: Scope of the compounds. Owing to the range of many variables, millions of highly substituted heteroaromatic compounds are embraced.

(2) The nature of the invention: The invention is a highly substituted heteroaromatic compounds.

(3) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and chemical reactivity (which is affected by determinants such as substituent effects, bonding, molecular geometry, etc) is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

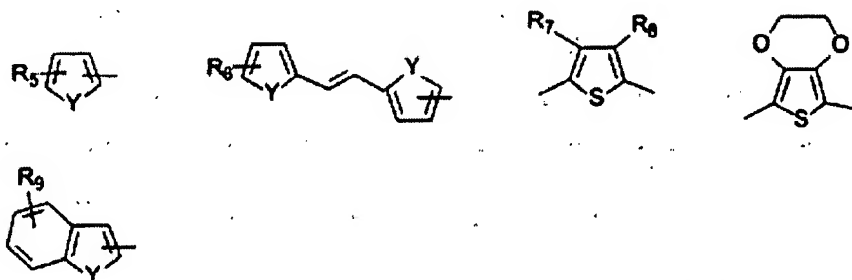
(4) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of application's general formula I and II. Pages 7-10 of the Specification describes starting materials and methods for synthesis of compounds wherein Het-2 being N-alkylated pyridinium, Het-1, Het-3, Het-4 being thienyl fused dioxanyl, pyridinium, and pyrrolyl, but does not describe or list any reagents wherein

compounds can be used to synthesis compounds where Het-1, Het-2, Het-3, Het-4 as listed above. There is limited evidence in the Specification of the example compounds that only covers no or a small portion of the substituents claimed of these formulae. Thus, there is no specific direction or guidance regarding said compounds specifically mentioned in Scope.

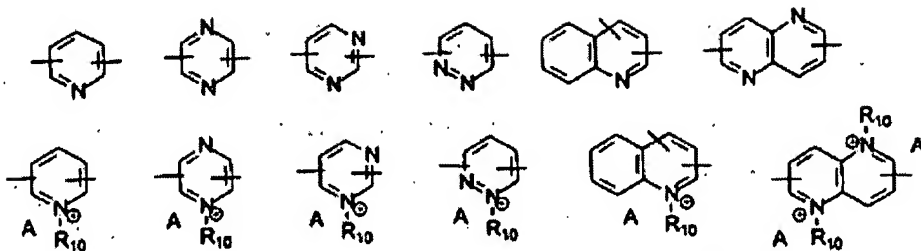
The availability of the starting material that is needed to prepare the invention as claimed is at issue here...As per MPEP 2164.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in *re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. In *re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(5) State of the Prior Art: These compounds are substituted heteroaromatic compounds wherein Het-1, Het-2, Het-3, Het-4=pyridinium, pyrrolyl, thienyl, phenyl, thioxazolyl, which are well documented in the art. So far as the examiner is aware, no substituted

heteroaromatic compounds of general formula I wherein Het-1, Het-2, Het-3, Het-4 equals:



wherein Y may be O, S, or NZ with Z = H, lower alkyl, and aryl; and wherein R₅, R₆, R₇, R₈, and R₉ are the same or different, and are selected from the group consisting of H, alkyl groups having from 1 to 18 carbon atoms, alkoxy, aminoalkyl, alkylhalide, hydroxyalkyl, alkyl groups containing hydroxy and amino functionalities, alkoxyalkyl, alkylsulfide, alkylthiol, alkylazide, alkylcarboxylic, alkylsulfonic, alkylisocyanate, alkylisothiocyanate, alkylalkene, alkylalkyne, aryl, formyl, and that can contain electronpoor ethenylic moieties such as maleimide, capable to react with nucleophilic groups such as -SH, and groups such as isothiocyanate capable to react with groups such as -NH₂; and Het-2 is selected among the following heterocyclic groups:



wherein R₁₀ is selected from the group consisting of H, alkyl groups having from 1 to 18 carbon atoms, alkoxy, aminoalkyl, alkylhalide, hydroxyalkyl, alkyl groups containing hydroxy and amino functionalities, alkoxyalkyl, alkylsulfide, alkylthiol, alkylazide, alkylcarboxylic, alkylsulfonic, alkylisocyanate, alkylisothiocyanate, alkylalkene, alkylalkyne, aryl, formyl, and that can contain electronpoor ethenyl moieties such as maleimide, capable to react with nucleophilic groups such as -SH, and groups such as isothiocyanate capable to react with groups such as -NH₂;

and A is selected among the anions alkylsulfonate, arylsulfonate, polyarenesulfonate, triflate, halide, sulfate, methosulfate, phosphate, polyphosphate;

and wherein n and m, the same or different may be 0,1,2;

and R₁, R₂, R₃, and R₄, the same or different, may be H, lower alkyl, alkoxyalkyl, aryl, cyano, alkoxycarbonyl, -(CR₁₁R₁₂)_p-Het, wherein 0 < p < 10, R₁₁ and R₁₂, the same or different, are selected from the group of H, lower alkyl, and Het may be Het-1 or Het-2 or Het-3.

(6) Working Examples: Applicant shows examples 1-3 on pages 6-10 but no working examples were shown wherein Het-1, Het-2, Het-3, Het-4 and substituents, as mentioned above, have been made or used of any kind.

(7) Skill of those in the art: The ordinary artisan is highly skilled, e.g. a masters or PhD level chemist.

(8) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claim Rejections - 35 USC § 102

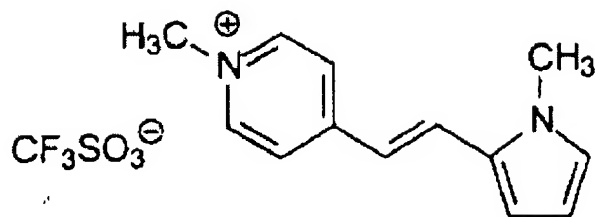
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

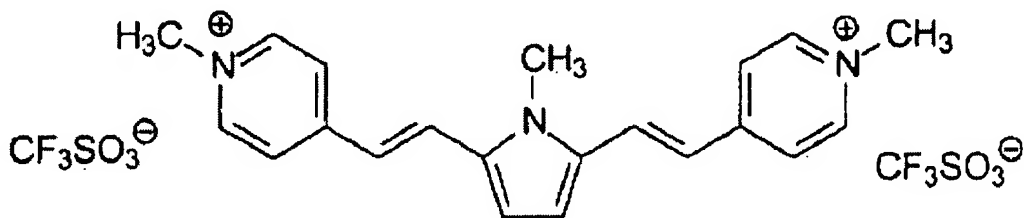
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 18 and 22-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Pagani et al (WO 01/70735 A1).

Pagani discloses compounds and compositions wherein Het-2=N-methyl pyridinium, Het-1=N-methyl pyrrolyl, and $R_{13}/R_{14}=H$, $n=1$ and $m,p,q=0$ (see page 6, compound (1) and entire document).

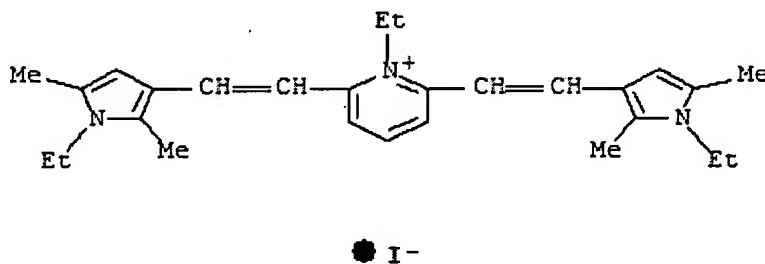


Pagani also discloses compounds and compositions wherein Het-2=N-methyl pyridinium, Het-1=N-methyl pyrrolyl, and $R_{13}/R_{14}/R_{19}/R_{20}=H$, $n,q=1$ and $m,p=0$ (see page 6, compound (3) and entire document).



Claims 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Phillips et al (US 3,376,297 A).

Phillips discloses compounds wherein Het-2=N-ethyl pyridinium, Het-1/Het-3=N-ethyl pyrrolyl, $n,m=1$, $p=0$, $R_{13}/R_{14}/R_{15}/R_{16}=H$ (see column 4, Table II, Example 27).



This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

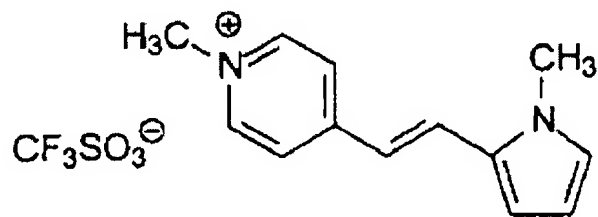
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

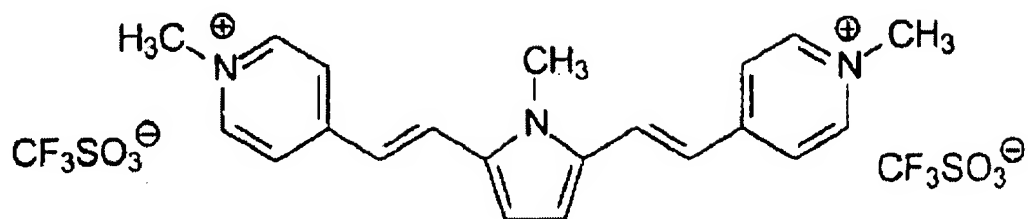
Claims 17-18 and 22-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 6-24 of copending Application No. 2003/0118916 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

The instant application discloses compounds and compositions of Formula I and II, wherein Het-2=N-methyl pyridinium, Het-1=N-methyl pyrrolyl, and $R_{13}/R_{14}=H$, $n=1$ and $m,p,q=0$. Also, the instant application discloses compounds and compositions of Formula I and II, Het-2=N-methyl pyridinium, Het-1=N-methyl pyrrolyl, and $R_{13}/R_{14}/R_{19}/R_{20}=H$, $n,q=1$ and $m,p=0$

Pagani discloses compounds and compositions wherein Het-2=N-methyl pyridinium, Het-1=N-methyl pyrrolyl, and $R_{13}/R_{14}=H$, $n=1$ and $m,p,q=0$ (see page 2, compound (1) and entire document).



Pagani also discloses compounds and compositions wherein Het-2=N-methyl pyridinium, Het-1=N-methyl pyrrolyl, and $R_{13}/R_{14}/R_{19}/R_{20}=H$, $n,q=1$ and $m,p=0$ (see page 3, compound (3) and entire document). Thus, obvious-type double patenting is rendered.



This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

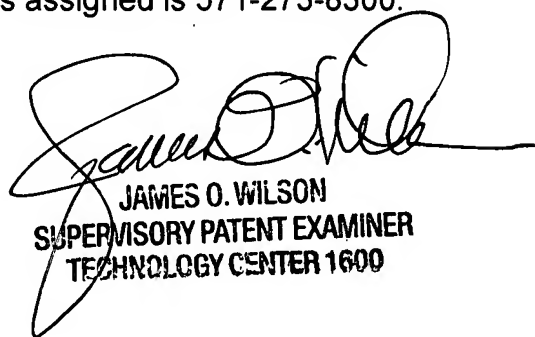
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



JM



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600